DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9338d

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 20, 2002

WL-40-02

Joseph I. Cheng, President
Taiwan Seafood and Fish Corporation
733 S. Gladys Ave.
Los Angeles, CA 90021

Dear Mr. Cheng:

We inspected your seafood processing facility, located at 733 South Gladys Avenue, Los Angeles, California 90021 on March 11 and 12, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fishery products described below to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. The deviations were as follows:

1. Since you have chosen to include corrective actions in your HACCP plan, your described corrective actions must be followed and be appropriate to comply with 21 CFR 123.7(a) and (b). However, your firm did not take a corrective action to control histamine (scombrotoxin) formation when your process for histamine-forming species deviated from your critical limit at the refrigerated storage critical control point. On March 11, 2002 our investigator observed that your walk-in cooler containing histamine-forming fishes such as fresh tuna and escolar was at 48°F in excess of two hours. During this time, various whole H&G and filleted tuna were measured with internal temperatures of 45°F to 48°F. Your firm failed to take corrective action as specified in your HACCP plan when cooler temperatures were observed to exceed their critical limit of [redacted] Your HACCP plan outlines specific actions to be taken and recorded when such a deviation occurs.

2. You must have a HACCP plan that lists monitoring procedures and frequencies for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for all products, including fresh histamine-forming species, lists monitoring procedures at the receiving and refrigerated storage critical control points that are not sufficient to control histamine formation. For example:

   A) The monitoring procedure at the receiving critical control point is not adequate to control receipt of temperature abused fishes. Specifically, the plan states that at least [redacted] fish per lot, and at least [redacted] fish from each case, will be checked for an internal temperature not to exceed [redacted] Monitoring of internal temperatures is no longer

considered a reliable method of control for fish that have been in transit for more than four hours. The guide suggests that at receipt by a secondary processor (including warehouse) the monitoring procedure, at the receiving critical control point for histamine-producing fish, may include the following:

> For fish delivered refrigerated (not frozen): Monitoring of the internal temperature of the fish throughout transportation;
> **OR**
> For fish delivered refrigerated (not frozen): Monitoring of the temperature of the truck or other carrier throughout transportation;
> **OR**
> For fish delivered refrigerated (not frozen): Monitoring of the internal temperature of a representative number of fish in the lot at the time of delivery (if transit time of four hours or less);
> **OR**
> For fish held under ice or chemical cooling media: Monitoring of the adequacy of ice or chemical cooling media at the time of delivery.

B) The monitoring procedure at the refrigerated storage critical control point (CCP) does not list the monitoring frequency of the "adequacy of ice" monitoring. During refrigerated storage of histamine-forming species, FDA recommends continuous monitoring of the temperature. You may either monitor the adequacy of ice cooling media twice a day, or monitor the temperature of the storage chamber continuously by means of a temperature data recorder or by using an alarm system.

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor cross-contamination from insanitary objects to food or food contact surfaces, as required by 21 CFR 123.11(b)(3) with sufficient frequency to ensure conformance with conditions and practices specified in 21 CFR Part 110 as follows:
    - filleted tuna loins being stored directly on plastic pallets that had numerous surfaces which are hard to clean and sanitize (21 CFR 110.80(b)(5);
    - use of a high pressure hose to clean the filleting room while there were uncovered tuna loins close to the same area (21 CFR 110.80(b)(5);
    - floor-to-ceiling plastic divider strips between the filleting room and the main room that were dragged over uncovered tuna loins on a pallet as they were moved to the cooler (21 CFR 110.80(b)(5).

Further, your firm did not monitor the safety of water that comes in contact with food or food contact surfaces, as required by 21 CFR 123.11(b)(1), with sufficient frequency to ensure conformance with conditions and practices specified in 21 CFR Part 110 as evidenced by the

following: a high pressure hose with an open end that is used for cleaning food contact surfaces was observed on the wet processing floor (21 CFR 110.37(b)(3)). However, on the second day of the inspection, we noted that your firm corrected this deviation and the hose was properly placed on a support hook.

Please be advised that in addition to the seafood HACCP requirements in 21 CFR Part 123, the regulations mandate that seafood processors monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance with current good manufacturing practice (CGMP) requirements for sanitation, set forth in 21 CFR Part 110, that are appropriate to the plant and to the product. Observations made during our inspection demonstrate that your firm was operating under insanitary conditions, without regard to CGMP for sanitation set forth in Part 110 and the sanitation monitoring requirement in Part 123.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You should take prompt action to correct this deviation. Failure to promptly do so may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may wish to include in your response documentation such as HACCP plans, corrective action forms, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections.

If you have any questions relating to this letter you should contact Robert B. McNab, Compliance Officer, at (949) 798-7709. Your written reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch
U. S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

Sincerely,

Alonza E. Cruse, Director
Los Angeles District

cc: Thomas K. Romano, Manager
Taiwan Seafood and Fish Corporation
733 S. Gladys Ave.
Los Angeles, CA 90021